

Congress of the United States
Washington, DC 20515

March 19, 2020

Dr. Stephen M. Hahn
Commissioner
U.S. Food & Drug Administration
10903 New Hampshire Ave.
Silver Spring, MD 20993-0002

Dear FDA Commissioner Hahn:

We write with extremely urgent concerns about the availability of reagents and other coronavirus (COVID-19) testing supplies at labs throughout the state of Wisconsin. We are hearing from hospitals across the state who are facing extreme challenges due to the lack of supply of reagents, swabs, and other supplies available to process collected specimens in labs across Wisconsin. We ask you to work with the Wisconsin Department of Health Services as they are working to ensure the state of Wisconsin has the supplies necessary to meet testing capacities at state laboratories, hospitals, commercial labs, and academic medical centers.

In response to recommendations from the federal government that hospitals ramp up testing, nearly every hospital and health system in Wisconsin has increased their ability to test by setting up curbside or other forms of rapid testing. However, the overall supply chain is not keeping up with either patient demand or testing capacity.

The Wisconsin State Laboratory of Hygiene (WSLH) and Milwaukee Health Department Laboratory (MHDL) have reported in the enclosed memo that "the number of specimens being received during the week of March 16, 2020 far exceeds their daily capacity." The memo goes on to say "WSLH & MHDL has a finite number of reagents and supplies available for this testing, and WSLH received 800 samples on March 16, 2020 and more than 1,000 just in the morning on March 17th. The nationwide supply chain for reagents and other testing supplies is very fragile as more laboratories begin testing."

For this reason, these labs are deciding to first process only the highest priority patients, meaning many patients will see significant delays in obtaining test results. Instead of rapid turnaround in test results, patients are waiting up to, and sometimes more than, a week to see results.

We have several hospitals that have already set up their own labs, and more are scheduled to come online in the coming days. However, they are unable to obtain the equipment and supplies necessary to complete testing, leaving a significant amount of untapped capacity.

This testing bottleneck is creating dire consequences for our hospitals and their staff. Importantly, these delays only increase the risk of COVID-19 spread. Further, they also have serious implications for the provision of health care as health care workers pulled out of the workforce may need to wait days for test results.

While we are extremely grateful for the expedited approval FDA has given laboratories and testing suppliers, **Wisconsin needs your help NOW to make sure the supply chain can keep up with our ability to test the public.** To assist with this, we need to know as soon as possible:

- What steps FDA is taking to ensure an adequate supply of reagents and other supplies.
- More information about FDA's efforts to distribute limited testing supplies to the different entities that are performing COVID-19 testing in Wisconsin, including commercial reference laboratories and state health labs, academic medical centers, and other entities in order to ensure that testing can continue as efficiently as possible.
- We have heard that suppliers may be redirecting supplies originally slated to go to Wisconsin to other states that have a higher number of confirmed COVID-19 cases or with larger population concentrations. If this is happening, what is the process by which this gets decided?

Our ability to monitor the spread of COVID-19 and effectively respond to this pandemic depends on adequate supplies to meet the expanding need to test patients. Thank you for your ongoing efforts.

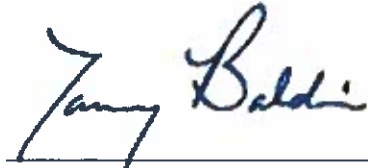
Sincerely,



Ron Kind
Member of Congress



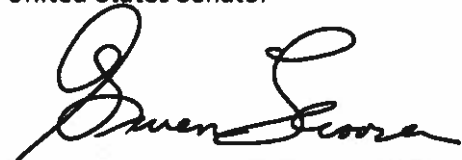
Ron Johnson
United States Senator



Tammy Baldwin
United States Senator



F. James Sensenbrenner, Jr.
Member of Congress



Gwen Moore
Member of Congress



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